



# Processed Apples Institute

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April 1, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
e-mail: [www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments)

RE: Registration of Food Facilities Under the Public Health Security  
and Bioterrorism Preparedness and Response Act of 2002  
**Docket No. 02N - 0276**

The Processed Apples Institute (PAI) is a trade association composed of companies producing apple products: juices, sauces, flavors, essences, etc. Our members produce a major portion of the apple juice and applesauce manufactured annually in the United States. PAI submits the following comments on the Food and Drug Administration's proposed regulation: Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which was published in the February 3, 2003, *Federal Register* (68 FR 5377).

Section 1.231 of the proposal indicates that registration must be either electronic (Internet) or by mail. PAI believes that facilities should be able to submit registration forms, updates and cancellations via facsimile. For those facilities without Internet access, especially foreign facilities, being able to submit registrations via facsimile would be quicker than regular mail.

In addition, FDA does not provide a clear procedure the Agency will use to notify a foreign facility that its products have been detained due to failure to register. Section 1.241 of the proposal outlines what happens if a facility fails to register, however, the procedure that the FDA will use to notify a foreign facility that its product has been detained due to lack of registration has not been defined.

Attached are PAI's comments submitted to the Office of Management and Budget (OMB) regarding the data used to develop the estimated costs for implementing the proposal.

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We appreciate your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Andrew G. Ebert". The signature is written in a cursive, flowing style.

Andrew G. Ebert  
President

Attachment